"We need to draw the line on unethical behavior. But let's draw it with an Etch-a-Sketch and don't be afraid to shake it a little."

Demystifying the Research Ethics Board

Agenda

- Overview of research ethics principles & procedures
- Overview of the research ethics approval process at the U of R
- Advice on completing the ethics application.

Core Principles

- Tri-Council Policy Statement 2 – Ethical Conduct for Research Involving Humans (2010; revisions in 2014)
- Respect for persons
- Concern for welfare
- Justice

Research Requiring Review

- Human participants
- Human biological materials

- **Approval must be obtained PRIOR** to data collection

Research Exempt from Review

- Publically available information
- Observation of people in public places
- Secondary use of anonymous information

Ethics Review

- REB exists to
  - protect participants and researchers
- REB works with (not against) researchers to ensure their research plan is ethically sound

Assessing Risk

- Determined on the basis of
  - the participants (vulnerability)
  - research requirements (emotional, legal, social, physical)
- Minimal Risk
  - *research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life.*
- Above Minimal Risk

Minimal Risk Applications

- Applications are reviewed by 2 REB members (Random selection)
- Also reviewed by the Chair
- Comments are returned to the applicant
- Either approved, approved with amendments or needs resubmission

Above Minimal Risk

- Applications are reviewed by the full REB at a monthly meeting
- May require a scholarly review

- 1 meeting per month

Multi-jurisdictional Research

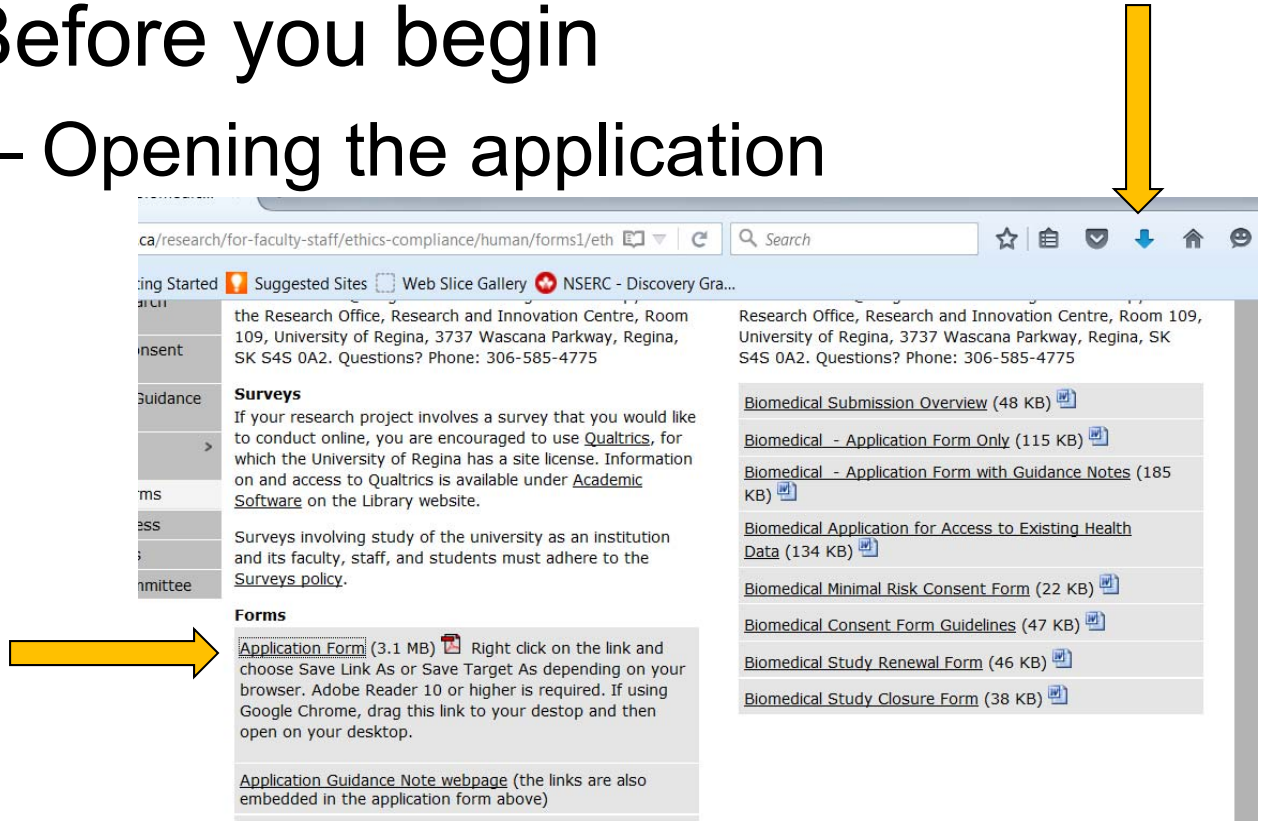
- Reciprocity Agreement
  - University of Saskatchewan
  - Saskatchewan Health Authority
  - Saskatchewan Polytechnic

Ethics Review Process

- Submit your completed (and signed) application to research.ethics@uregina.ca
- Ensure your supervisor has reviewed and signed off on your application
- Review process usually takes about – 4 weeks. Plan for it!!

REB Application Form

- Before you begin
  - Opening the application



REB Application Form

- Before you begin
  - Read the entire application through
  - Dynamic Form
  - Refer to the guidance notes

REB Application Form

- Part 1 Identification

PART 1: IDENTIFICATION	
1.1	**Project Title** GN 1.1
1.2	**Principal Investigator** GN 1.2 Full Name: Mailing Address: Email: Phone: NSID number (U of S faculty only):
1.3	**University/Institutional Affiliation of Principal Investigator** GN 1.3 Position: Department: Division:
1.4	If this is a student/graduate/resident project, please provide the following information: GN 1.4 a) Student Name(s) and Student ID or NSID (s): b) Supervisor Name:
1.5	**Project Personnel (include graduates/post graduates/residents):** GN 1.5 Add Personnel Remove Last Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:
1.6	**Primary Contact Person for Correspondence (if different than Section 1.2)** GN 1.6 Full Name: Mailing Address: Email: Phone:

1.7	Research Site(s) where project will be carried out:
1.8	1.8.1 Proposed Project Period: GN 1.8 From (MM/DD/YY) To (MM/DD/YY)
1.9	**1.9.1 Has this project applied for and/or received ethical approval from any other Research Ethics Board? Will you be seeking REB approval through the Sask. ethics harmonization process?** GN 1.9 ☒ Yes ☐ No If yes, specify where and submit a copy of the certificate of approval: **1.9.2 Please be advised that approvals may need to be sought if you are collecting data from schools, within health regions and may be required from other organizations, agencies, or community groups. Will you be contacting potential participants or collecting data from any such organizations?** GN 1.9.2 ☒ Yes ☐ No If yes selected then open: Specify where, provide details and submit a copy of the certificate or letter of approval (when obtained). Please provide justification if you do not plan to seek approval.
1.10	1.10.1 Status of Funds: GN 1.10 ☐ Awarded ☐ Pending ☐ **Unfunded**

REB Application Form

- Part 2 Conflict of Interest

PART 2: CONFLICT OF INTEREST	
2.1	**2.1.1 Is there any real, potential or perceived conflict of interest (any personal or financial interest in the conduct or outcome of this project)?** GN 2.1 **2.1.2 Will any of the researcher(s), members of the research team and/or their immediate family members:** · Receive personal benefits in connection with this project over and above the direct costs of conducting the project, such as remuneration or employment? · Receive significant payments of other sorts from the sponsor such as grants, compensation in the form of equipment or supplies or retainers for ongoing consultation and honoraria? · Have a non-financial relationship with a sponsor (such as unpaid consultant, board membership, advisor or other non-financial interest? · Have any direct involvement with the sponsor such as stock ownership, stock options or board membership. · Hold patents, trademarks, copyrights, licensing agreements or intellectual property rights linked in any way to this project or the sponsor? · Have any other relationship, financial or non-financial, that if not disclosed, could be construed as a conflict of interest? ☒ Yes ☐ No **Please describe the personal benefits or relationship.**
2.2	Have any restrictions regarding access to or disclosure of information (during or at the end of the project) been placed on the investigators? This includes controls placed by the sponsor, funding body or advisory committee. ☐ Yes ☐ No
2.3	Please describe the arrangement and discuss the implications of any potential conflict of interest. Please describe how the conflict will be reduced, managed or eliminated as well as what additional protections have been put in place to protect project participants. The conflict of interest and how that conflict is being managed should be disclosed in the letter of information/ consent to participants.

REB Application Form

- Part 3 Brief Overview of Research Project

PART 3: BRIEF OVERVIEW OF RESEARCH PROJECT	
3.1	**Briefly describe the project, its objectives and potential significance (250-500 words):** GN 3.1 projectDescription
3.2	**Provide a description of research design and methods to be used:** GN 3.2
3.3	Provide details regarding the duration and location of data collection event(s): GN 3.3 ☐ Questionnaire ☐ Participant Observation ☐ Individual Interviews ☐ Focus Groups ☐ Group Interview ☐ Non-invasive physical measurements ☐ Video/audio recording ☐ Secondary use of data or analysis of existing data ☐ Home Visits ☐ Ethnography ☐ Other:

REB Application Form

- Part 4 Project Details

PART 4: PROJECT DETAILS	
4.1	4.1.1 Will you have any internet-based interaction with participants? GN 4.1 ☒ Yes ☐ No 4.1.2 If you are using a third party research tool, website survey software, transaction log tools, screen capturing software, or masked survey sites, how will you ensure the security of data gathered at that site? 4.1.3 Describe how permission to use any third party owned site(s) will be obtained, if applicable: 4.1.4 How will you protect the privacy and confidentiality of participants who may be identified by email addresses, IP addresses, and identifying information that may be captured by the system during your interactions with these participants? 4.1.5 If you do not plan to identify yourself and your position as a researcher to the participants, from the onset of the research study, explain why you are not doing so, at what point you will disclose that you are a researcher, provide details of debriefing procedures, if any, and if participants will be given a way to opt out, if applicable:
4.2	4.2.1 Will your research involve Aboriginal Peoples including First Nations, Inuit and Métis peoples? GN 4.2 ☒ Yes ☐ No 4.2.2 Please outline the plans to obtain community engagement for this project. Describe the nature, and extent of the community engagement as determined jointly by the researcher and relevant community. If no community consent is being sought, please justify. 4.2.3 Describe any relevant customs and codes of research practice that apply to the particular community or communities affected by the research: 4.2.4 Will a research agreement between the researcher and community be prepared?

	4.2.5 How will your research plan consider mutual benefit to the participating community, support capacity building through enhancement of the skills of community personnel, and the recognition of the role of elders and other knowledge holders? 4.2.6 Will community representatives have the opportunity to participate in the interpretation of the data and the review of research finding before the completion of any reports or publications? How will final results of the project be shared with the participating community?
4.3	4.3.1 Will the project involve community-based participatory research? GN 4.3 ☒ Yes ☐ No 4.3.2 Please outline the plans to obtain community engagement for this project. Describe the nature, and extent of the community engagement as determined jointly by the researcher and relevant community. If no community consent is being sought, please justify. 4.3.3 Describe the organizational structure and community processes required to obtain approval within the specific community or communities. 4.3.4 Will a research agreement between the researcher and community be prepared? This should outline the goals of the project, principles of partnership, decision-making processes, roles and responsibilities of partners and guidelines for how the partnership will handle and disseminate data. 4.3.5 Will community representatives have the opportunity to participate in the interpretation of the data and the review of research finding before the completion of any reports or publications? How will final results of the project be shared with the participating community?
4.4	Will deception of any kind be necessary in this project? GN 4.4 ☒ Yes ☐ No Please explain and describe the protocol for debriefing and re-consenting of participants upon completion.
4.5	Indicate how the participants will be debriefed following their participation (if applicable), and describe how the information on the results of the research will be made available to participants once the study has ended. Debriefing is particularly important if deception has been used. GN 4.5
4.6	Will participants be compensated? GN 4.6 ☒ Yes ☐ No Please include details:
4.7	4.7.1 Will participants be anonymous in the data gathering phase of the study? (Anonymous means that no link can be established between the participant and the research - no one including the researcher knows who has participated in the research): ☒ Yes ☐ No 4.7.3 If yes, are there any limits to confidentiality: ☐ Limits due to the nature of group activities (e.g. focus groups): the researcher cannot guarantee confidentiality ☐ Limits due to context: individual participants could be identified because of the nature or size of the sample or because of their relationship with the researcher. ☐ Limits due to selection: procedures for recruiting or selecting participants may compromise the confidentiality of participants (e.g. participants are referred to the study by a person outside the research team) ☐ Other:

REB Application Form

- Part 5 Estimation of Risks and Benefits

PART 5: ESTIMATION OF RISKS AND BENEFITS	
5.1	**5.1.1 Do you consider this project to be:** GN 5.1 ☐ Minimal Risk ☐ Above Minimal Risk **5.1.2 Indicate if the participants might experience any of the following:** **Risk of psychological or emotional harm or discomfort (e.g. trauma, anxiety, stress)** **Legal repercussions for participating in the study(e.g. possibility of being sued, charged with criminal activity, disclosure of past or future criminal activities, etc.)** **Social repercussions (e.g. ostracized, being negatively judged by peers or employer, fired from your job)** **Risk of physical harm or discomfort (e.g. falling, muscle pain, tiredness, weakness, nausea)** **5.1.3 Describe how the risk will be managed (including an explanation as to why an alternative approached could not be used). If appropriate, identify any resources, e.g. physician or counselor, to which participants can be referred.** GN 5.1.3 **5.1.4 If above minimal risk, what are the likely benefits of the research to the researcher, participant, the research community and society that would justify asking participants to participate?** GN 5.1.4

REB Application Form

- Part 6 Participant Recruitment

PART 6: PARTICIPANT RECRUITMENT	
6.1	Describe the participants and the criteria for their inclusion or exclusion. Indicate the number of participants and a brief rationale for the intended number of participants: GN 6.1
6.2	6.2.1 Provide a detailed description of the method of recruitment. GN 6.2 6.2.2 How will prospective participants be identified? 6.2.3 Who will contact prospective participants? Describe the source of the contact information, how they will be contacted and as applicable, who originally collected the contact information. Ensure any letters of initial contact or other recruitment materials are attached, e.g. advertisements. flyers, telephone script, etc.
6.3	In cases where the research involves special or vulnerable populations, distinct cultural groups, or in cases where the research is above minimal risk, the researcher should describe their experience or training in working with the population. If none of these criteria apply, this section may be omitted. GN 6.3
6.4	Where relevant, please explain any relationship (pre-existing, current or expected to have) between the researcher(s) and the researched (e.g. instructor-student, manager-employee, co-workers, family members/intimate relationships, etc). Please pay special attention to relationships in which there may be a power differential. Describe any safeguards and procedures to prevent possible undue influence, coercion or inducement. GN 6.4

REB Application Form

- Part 7 Consent Process

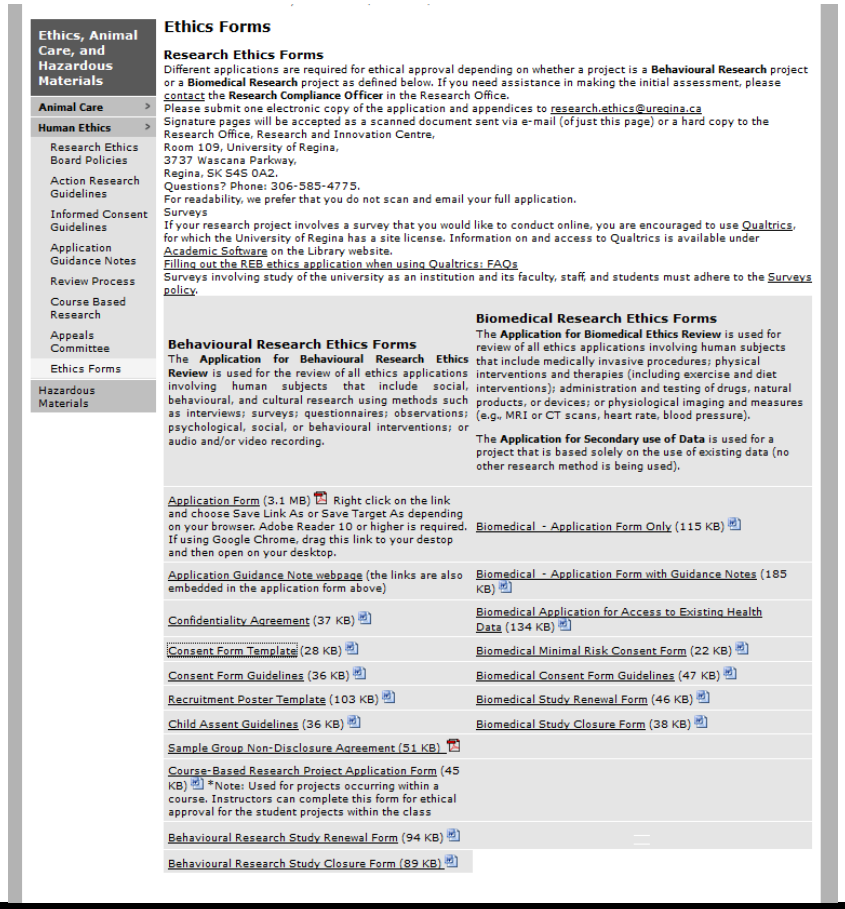
PART 7: CONSENT PROCESS	
7.1	**Describe the process that will be used to obtain informed consent. Please note that it is the content of the consent, not the format that is important. If the research involves collection of personally identifiable information from a research participant or extraction of personally identifiable information from an existing database, please describe how consent from the individuals or authorization from the data custodian will be obtained. If there will be no written consent, please provide a rationale for oral or implied consent (e.g., cultural appropriateness, online questionnaire, etc.) and explain how consent will be recorded.** **7.1.1 Describe the consent process. GN 7.1** **7.1.2 Who will ask for consent?** **7.1.3 Where, and under what circumstances will consent be obtained?** **7.1.4 Describe any situation in which the renewal of consent for this research might be appropriate and how this would take place (e.g. longitudinal studies, multiple data collection events, etc.).**
7.2	**If any or all of the participants are children and/or are not competent to consent, describe the process by which capacity/competency will be assessed, the proposed alternate source of consent - including any permission/ information letter to be provided to the person(s) providing the alternate consent - as well as the assent process for participants. GN 7.2**
7.3	**Describe your plans for providing project results to the participant? GN 7.3**
7.4	**How and when are participants informed of the right to withdraw? What procedures will be followed for participants who wish to withdraw at any point during the study? GN 7.4**

REB Application Form

- Part 8 Data Security and Storage

PART 8: DATA SECURITY AND STORAGE	
Indicate the procedures you plan to implement to safeguard and store the data. Identify the person who will be assuming responsibility for data storage (University policy requires the researcher or the supervisor, in the case of student research, to securely store the data at the University for a minimum of five years upon the completion of the study. For more information see U of S Responsible Conduct of Research Policy or U of R Records and Information Management Policy.	
8.1	**Who will conduct the data collection? GN 8.1**
8.2	**Who will have access to the original data of the study? GN 8.2**
8.3	**How will confidentiality of original data be maintained as well as preserving or destroying data after the research is completed. For all data (e.g. paper records, audio or visual recordings, electronic recordings), indicate the: GN 8.3**
	8.3.1 Person responsible for data storage:
	8.3.2 Data security during transportation from collection site:
	8.3.3 Means and location of storage (e.g. a locked filing cabinet, password protected computer files, encryption):
	8.3.4 Time duration of storage (Must be > 5 Years):
	8.3.5 Final disposition (archive, shredding, electronic file deletion):
8.4	**Indicate how the data collected is intended to be used (thesis, journal articles, conference presentation, media, etc). GN 8.4**

The Consent Form



Ethics, Animal Care, and Hazardous Materials

- Animal Care
- Human Ethics
  - Research Ethics Board Policies
  - Action Research Guidelines
  - Informed Consent Guidelines
  - Application Guidance Notes
  - Review Process
  - Course Based Research
  - Appeals Committee
  - Ethics Forms
- Hazardous Materials

Ethics Forms

Research Ethics Forms

Different applications are required for ethical approval depending on whether a project is a **Behavioural Research** project or a **Biomedical Research** project as defined below. If you need assistance in making the initial assessment, please contact the **Research Compliance Officer** in the Research Office.
Please submit one electronic copy of the application and appendices to research.ethics@uregina.ca
Signature pages will be accepted as a scanned document sent via e-mail (of just this page) or a hard copy to the Research Office, Research and Innovation Centre,
Room 109, University of Regina,
3737 Wascana Parkway,
Regina, SK S4S 0A2.
Questions? Phone: 306-585-4775.
For readability, we prefer that you do not scan and email your full application.
Surveys
If your research project involves a survey that you would like to conduct online, you are encouraged to use Qualtrics, for which the University of Regina has a site license. Information on and access to Qualtrics is available under Academic Software on the Library website.
Filling out the REB ethics application when using Qualtrics: FAQs
Surveys involving study of the university as an institution and its faculty, staff, and students must adhere to the Surveys policy.

Behavioural Research Ethics Forms

The **Application for Behavioural Research Ethics Review** is used for the review of all ethics applications involving human subjects that include social, behavioural, and cultural research using methods such as interviews; surveys; questionnaires; observations; psychological, social, or behavioural interventions; or audio and/or video recording.

- Application Form (3.1 MB) Right click on the link and choose Save Link As or Save Target As depending on your browser. Adobe Reader 10 or higher is required. If using Google Chrome, drag this link to your destop and then open on your desktop.
- Application Guidance Note webpage (the links are also embedded in the application form above)
- Confidentiality Agreement (37 KB)
- Consent Form Template (28 KB)
- Consent Form Guidelines (36 KB)
- Recruitment Poster Template (103 KB)
- Child Assent Guidelines (36 KB)
- Sample Group Non-Disclosure Agreement (51 KB)
- Course-Based Research Project Application Form (45 KB) *Note: Used for projects occurring within a course. Instructors can complete this form for ethical approval for the student projects within the class
- Behavioural Research Study Renewal Form (94 KB)
- Behavioural Research Study Closure Form (89 KB)

Biomedical Research Ethics Forms

The **Application for Biomedical Ethics Review** is used for review of all ethics applications involving human subjects that include medically invasive procedures; physical interventions and therapies (including exercise and diet interventions); administration and testing of drugs, natural products, or devices; or physiological imaging and measures (e.g., MRI or CT scans, heart rate, blood pressure).

The **Application for Secondary use of Data** is used for a project that is based solely on the use of existing data (no other research method is being used).

- Biomedical - Application Form Only (115 KB)
- Biomedical - Application Form with Guidance Notes (185 KB)
- Biomedical Application for Access to Existing Health Data (134 KB)
- Biomedical Minimal Risk Consent Form (22 KB)
- Biomedical Consent Form Guidelines (47 KB)
- Biomedical Study Renewal Form (46 KB)
- Biomedical Study Closure Form (38 KB)

For more information …

- TCPS 2
  - http://pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html
- TCPS 2 Course on Research Ethics (CORE)
  - http://tcps2core.ca/welcome
- CIHR Guidelines for Health Research Involving Aboriginal People
  - http://www.cihr-irsc.gc.ca/e/29134.html
- The First Nations Principles of OCAP®
  - https://fnigc.ca/ocap